IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., FERRING B.V., and FERRING INTERNATIONAL CENTER S.A.,	)	
Plaintiffs,	)	C.A. No. 17-479-GMS
v.	)	
SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, and ALLERGAN, INC.,	)	Redacted Version of D.I. 18
Defendants.	)	

AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Ferring Pharmaceuticals Inc., Ferring B.V., and Ferring International Center S.A. (collectively, "Ferring") bring this action against Defendants Serenity Pharmaceuticals, LLC, Reprise Biopharmaceutics, LLC, and Allergan, Inc., (collectively, "Defendants") for declaratory judgment of invalidity, unenforceability, and non-infringement of United States Patent No. 7,405,203, United States Patent No. 7,579,321, and United States Patent No. 7,799,761 (collectively, the "Patents in Suit"), and allege as follows:

THE PARTIES

1. Plaintiff Ferring Pharmaceuticals Inc. ("Ferring Pharma") is a privately-held Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054. Ferring Pharma is owned by Ferring Holding, Inc., which is owned by Ferring B.V.

2. Plaintiff Ferring B.V. is a Dutch private limited liability company having its registered office at Polarisavenue 144, 2132 JX Hoofddorp, The Netherlands.

3. Plaintiff Ferring International Center S.A. ("FICSA") is a Swiss private limited liability company having its principal place of business at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland.

4. Ferring is engaged in business and research and development activities of, *inter alia*, the drug desmopressin, which was first developed in the 1970s.

5. On information and belief, Defendant Serenity Pharmaceuticals, LLC, ("Serenity") is organized under the laws of the State of Delaware, and has its principal place of business at 105 Hawk Court, Milford, Pennsylvania, 18337. On information and belief, Serenity also maintains an address at 120 North Main Street, Suite 400, New City, New York 10956.

6. On information and belief, Serenity is in the business of, *inter alia*, developing products that address urinary conditions, and has received regulatory approval for a desmopressin nasal spray to treat nocturia in adults, which Serenity intends to market and sell in the United States under the tradename NOCTIVA.

7. On information and belief, Defendant Reprise Biopharmaceutics, LLC ("Reprise") is organized under the laws of the State of New York, and has its principal place of business at 120 North Main Street, Suite 400, New City, New York, 10956.

8. On information and belief, Reprise is and has been a holding company with five members, including Drs. Seymour H. Fein and Ronald V. Nardi, created for the sole purpose of holding Dr. Fein's intellectual property (including the Patents in Suit).

9. On information and belief, Defendant Allergan, Inc. ("Allergan") is organized under the laws of the State of Delaware, and has its principal place of business at 2525 Dupont

Dr., Irvine, California, 92612. On information and belief, Allergan sells and offers for sale prescription pharmaceuticals subject to regulations by the U.S. Food and Drug Administration ("FDA").

PERSONAL JURISDICTION AND VENUE

10. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 et seq.

Personal Jurisdiction over Serenity

11. This Court has personal jurisdiction over Serenity by virtue of, *inter alia*, the fact that Serenity is a Delaware limited liability company. By forming a limited liability company in Delaware, Serenity has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware.

Personal Jurisdiction over Allergan

12. This Court has personal jurisdiction over Allergan by virtue of, *inter alia*, the fact that Allergan is incorporated in the state of Delaware. By incorporating in Delaware, Allergan has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware.

13. The Court also has personal jurisdiction over Allergan because Allergan has affirmatively availed itself of the jurisdiction of this Court by, *inter alia*, asserting claims for patent infringement in the District. *See, e.g., Allergan, Inc. v. TWi Pharmaceuticals, Inc. et al.*, 16-cv-00620-GMS (D. Del., filed July 7, 2016); *Allergan, Inc. et al. v. Somerset Therapeutics, LLC*, Case No. 16-cv-00392-GMS (D. Del., filed May 26, 2016); *Allergan, Inc. v. InnoPharma, Inc. et al.*, Case No. 15-cv-00815-SLR (D. Del., filed Sept. 14, 2015).

Personal Jurisdiction over Reprise

14. On information and belief, Dr. Seymour Fein, the alleged inventor of the Patents in Suit, and others formed Serenity Pharmaceuticals Corp. (the predecessor of Defendant Serenity) in Delaware on December 13, 2006, and related patent holding company, Defendant Reprise, in New York, on January 2, 2007.

15. On information and belief, Dr. Fein assigned his rights, title, and interest in the Patents in Suit to Reprise on March 1, 2007. Assignments of U.S. Application No. 11/744,615 ("the '615 Application"), which matured into United States Patent No. 7,405,203, and U.S. Application No. 10/706,100 ("the '100 Application"), which matured into United States Patent No. 7,799,761, to "Reprise Pharmaceuticals, LLC" were recorded in the United States Patent and Trademark Office ("PTO") assignment database at reel/frame 020990/0237 (executed on March 1, 2007; recorded on May, 23, 2008). Corrective assignments were recorded at reel/frame 021121/0562 (also indicating an execution date of March 1, 2007; recorded on June 19, 2008) to correct the assignee of the '615 Application and the '100 Application from Reprise Pharmaceuticals, LLC to Defendant Reprise. An assignment of U.S. Application No. 12/173,074 ("the '074 Application"), which matured into U.S. Patent No. 7,579,321, to Defendant Reprise was recorded at reel/frame 022954/0040 (executed on March 1, 2007; recorded on July 14, 2009), with a corrective assignment being recorded at reel/frame 023128/0258 (executed on March 1, 2009; recorded on August 21, 2009) to correct the assignee's address. These assignments (collectively referred to as "the Fein-Reprise Assignments") were signed by Dr. Fein as the assignor and by Dr. Fein as Managing Member of assignee Reprise.

16. On information and belief, Reprise exclusively licensed the Patents in Suit to Serenity Pharmaceuticals Corp. as of May 2007.

17. On information and belief, Dr. Fein formed Defendant Serenity in Delaware in November 2009, which is the successor-in-interest to Serenity Pharmaceuticals Corp. On information and belief, Defendant Serenity became an exclusive licensee of the Patents in Suit.

18. On information and belief, Serenity, by virtue of its complete control over Reprise, caused Reprise to transfer all of Reprise's right, title, and interest in the Patents in Suit to Allergan in the "Reprise-Serenity-Allergan Agreement" referred to in § 2.1(a)(ii) of the "License, Transfer, and Development Agreement by and among Serenity and Defendant Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC," dated March 31, 2010 ("the Serenity-Allergan Agreement"). A true and correct copy of a redacted version of the Serenity-Allergan Agreement is available from the United States Securities and Exchange Commission ("SEC" at www.sec.gov) and is attached as Exhibit A.

19. An assignment of the Patents in Suit from Reprise to Defendant Allergan was signed by Dr. Fein and was recorded at reel/frame 024412/0072 (executed on May 18, 2010; recorded on May 19, 2010).

20. A press release dated March 6, 2017 issued by Serenity stated that, "Serenity and Allergan have agreed to terminate their global agreement for the development and commercialization of Noctiva following a 90-day transition period." A true and correct copy of the March 6, 2017, press release is attached as Exhibit B.

21. On information and belief, upon termination of the Agreement, all right, title, and interest in the Patents in Suit was to revert to Serenity and/or Reprise.

22. On information and belief, Allergan is currently the owner by assignment of the Patents in Suit.

23. On information and belief, Serenity is and has been an exclusive licensee of the Patents in Suit.

24. On information and belief, Serenity and Reprise have overlapping founders, principals, and management, which include Dr. Seymour Fein. On information and belief, Dr. Fein maintains equity stakes in Serenity and Reprise. On information and belief, Dr. Fein exerts control over Serenity and Reprise.

25. On information and belief, Reprise is the agent, affiliate, and/or representative of, and/or acts in concert with, Serenity for activities related to the Patents in Suit.

26. On information and belief, Dr. Fein formed Reprise solely for the purpose holding his intellectual property rights relating to desmopressin, including the Patents in Suit.

27. On information and belief, Reprise has no corporate function other than to serve as a holding company for Dr. Fein's patent rights.

28. On information and belief, Reprise is an agent of Serenity and Dr. Seymour Fein for the purpose of holding the Patents in Suit.

29. On information and belief, Serenity is an agent of Reprise and Dr. Fein for the purpose of monetizing the Patents in Suit.

30. In a pending action in the U.S. District Court for the Southern District of New York (*Ferring B.V. et al. v. Allergan, Inc., et al.*, Case No. 12-cv-2650-RWS (S.D.N.Y., filed Apr. 5, 2012)) ("the Southern District of New York Action"), defendants Serenity, Reprise, and Dr. Fein have acted jointly and in concert and have been represented by the same attorneys.

31. [redacted]

[redacted]

32. On information and belief, Reprise and Serenity operate in lock-step to accomplish the goals of each other as well as Dr. Fein.

33. On information and belief, the day-to-day management of Reprise, to the extent there is anything to be managed, is handled by Dr. Fein, and Dr. Fein is heavily involved in the management of the day-to-day operations of Serenity, where he has been an equity shareholder, Chief Scientific Officer, and member of a five-person "leadership team," according to Serenity's website.

34. On information and belief, Reprise has no significant financing; however, Dr. Fein has used Reprise to license rights to the Patents in Suit to Serenity for the purpose of monetizing the Patents in Suit (i.e., securing venture funding for Serenity) for the benefit of Serenity, Reprise, and himself.

35. On information and belief, Reprise simply is used as a holding company: Dr. Fein obtains rights to intellectual property and decides to transfer those rights to Reprise, which has then licensed or assigned rights to Serenity or Allergan for purposes of monetizing those rights.

36. On information and belief, the process by which Serenity has derived its business has been that Dr. Fein individually or Dr. Fein and Dr. Samuel Herschkowitz jointly have obtained rights to intellectual property, have decided to transfer those rights to Serenity or

Allergan for purposes of monetizing those rights, namely by using those rights to entice Allergan to join them in a co-development program for pharmaceutical products.

37. On information and belief, Reprise is an "Affiliate" of Serenity in the Serenity-Allergan Agreement, and thus agreed, along with Serenity, to indemnify Allergan against certain losses.

38. Pursuant to the Serenity-Allergan Agreement, "Affiliate" is defined as follows:

> "Affiliate" means a corporation, partnership, trust, or other entity that . . . is controlled by, or is under common control with a specified Party . . . . For such purposes, "control," "controlled by," and "under common control with" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract, or otherwise. In the case of a corporation or other entity, the direct or indirect ownership of fifty percent (50%) or more of its outstanding voting shares or the ability otherwise to elect a majority of the board of directors or other managing authority of the entity shall in any event be presumptively deemed to confer control . . . .

39. On information and belief, Reprise is an Affiliate of Serenity under the Serenity-Allergan Agreement because Reprise either: (a) is controlled by Serenity because Serenity has the power to direct or cause the direction of the management or policies of Reprise through the activities of Dr. Seymour Fein through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract, or otherwise; or (b) is under common control with Serenity because Dr. Seymour Fein has the power to direct or cause the direction of the management and policies of both Reprise and Serenity through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract, or otherwise.

40. Under the Serenity-Allergan Agreement, Serenity and its Affiliates indemnified Allergan against certain losses:

> Serenity and its Affiliates shall defend, indemnify, and hold harmless Allergan . . . from and against any and all damages, losses, suits, proceedings, liabilities, . . . , or judgments . . . of any kind ("Losses") arising out of a claim by a Third Party arising out of, resulting from or relating to: [Serenity's gross negligence, material breach, or] any allegation that the manufacture, use, sale, offer for sale, or importation of the Product . . . misappropriates the intellectual property rights of any Third Party . . . .

41. According to the USPTO assignment database, the only assignments that Reprise has been a party to, involve the Patents in Suit or other desmopressin-related patents naming Dr. Fein as an inventor.

42. On information and belief, the only contracts that Reprise has entered into with respect to the Patents in Suit are: (1) the Fein-Reprise Assignments; (2) an exclusive license from Reprise to Serenity in 2007; and (3) the Reprise-Serenity-Allergan Agreement in 2010.

43. On information and belief, since the assignment from Dr. Fein in 2007, Reprise has entered into patent assignments and licenses exclusively with entities that are organized under the laws of Delaware: Serenity and Allergan.

44. On information and belief, Reprise has acted jointly or in concert with Serenity and/or Allergan to threaten Plaintiff Ferring Pharma, a Delaware corporation, with a patent infringement action.

45. On information and belief, the jurisdictional contacts of Serenity are the jurisdictional contacts of Reprise as each operates as the agent of the other and of Dr. Fein.

46. The Fein-Reprise Assignments provide:

> The undersigned agrees to assist the Company, at the Company's request from time to time and at the Company's expense, to obtain and enforce patents, copyrights or other proprietary rights with respect to the Inventions in any and all countries. The undersigned will execute all documents reasonably necessary or appropriate for this purpose. At the Company's request, the undersigned will advise or give testimony in any

> proceeding relating to the ownership, validity or scope of any such Intellectual Property Rights.

The "undersigned" is Dr. Fein, and "the Company" is Reprise.

47. On information and belief, any transfer of patent rights from Reprise to another entity would be subject to the rights and obligations of the Fein-Reprise Assignments.

48. On information and belief, Reprise has and/or had at the time this lawsuit was filed, an obligation to request Dr. Fein's participation in patent-related proceedings, including enforcement actions involving Reprise's assignees or licensees (i.e., Delaware entities Serenity and Allergan).

49. On information and belief, Reprise has consented to personal jurisdiction in Delaware at least because of its obligation to request Dr. Fein's participation in patent-related actions involving Reprise's assignees or licensees (i.e., Delaware entities Serenity and Allergan).

50. On information and belief, Reprise has consented to personal jurisdiction in Delaware at least because Reprise, along with Serenity, indemnified Allergan, an entity organized under the laws of Delaware, against losses in connection with patent-related claims in the Serenity-Allergan Agreement.

51. This Court has personal jurisdiction over Reprise at least because Reprise operates as the agent of Serenity and/or Dr. Fein, it has acted in concert with Serenity and Allergan to threaten enforcement of the Patents in Suit against Ferring, a Delaware corporation, and it has consented to jurisdiction through its dealings with Serenity and Allergan, including by indemnifying Allergan.

52. For at least the reasons set forth above in paragraphs 14-51, this Court has personal jurisdiction over Reprise.

53. For at least the reasons set forth above in paragraphs 1-52, venue is proper in this District under 28 U.S.C. §§ 1391 or 1400(b).

THE PATENTS IN SUIT

54. On July 29, 2008, the PTO issued United States Patent No. 7,405,203, and, on April 12, 2011, the PTO issued Ex Parte Reexamination Certificate, No. US 7,405,203 C1 (collectively, "the '203 patent"). The '203 patent bears the title, "Pharmaceutical Compositions Including Low Dosages of Desmopressin." A true and correct copy of the '203 patent is attached as Exhibit C.

55. On August 25, 2009, the PTO issued United States Patent No. 7,579,321 ("the '321 patent"). The '321 patent bears the title, "Pharmaceutical Compositions Including Low Dosages of Desmopressin." A true and correct copy of the '321 patent is attached as Exhibit D.

56. On September 21, 2010, the PTO issued United States Patent No. 7,799,761 ("the '761 patent"). The '761 patent bears the title, "Pharmaceutical Compositions Including Low Dosages of Desmopressin." A true and correct copy of the '761 patent is attached as Exhibit E.

57. On May 7, 2002, Ferring B.V. filed Great Britain Patent Application No. 0210397.6 ("GB '397"). No inventors were named in GB '397.

58. On September 20, 2002, Ferring B.V. filed PCT/1B02/04036 ("PCT '036") claiming priority to GB '397. PCT '036 published as WO2003094885 A1 ("WO '885") on November 20, 2003.

59. On May 7, 2003, Ferring B.V. filed a second PCT application, PCT/IB03/02368 ("PCT '368"), claiming priority to GB '397. Multiple United States patents claim priority to PCT '368—including U.S. Patent No. 7,560,429, U.S. Patent No. 7,947,654, U.S. Patent No.

8,802,624, U.S. Patent No. 9,220,747, and U.S. Patent No. 9,504,647—all of which are assigned to Ferring B.V.

60. On May 6, 2003, Dr. Seymour Fein filed PCT/US03/14463 ("PCT '463"), which included a priority claim to GB '397.

61. PCT '463 copied almost verbatim the specification of Ferring's PCT '036 and GB '397.

62. The '203 patent issued from U.S. Application No. 11/744,615, which is a division of the '100 Application, which is a continuation-in-part of PCT '463.

63. The '203 patent purports to claim priority to PCT '463, which purports to claim priority to Ferring's GB '397.

64. The '203 patent lists Dr. Fein as the sole inventor.

65. Independent claim 1 of the '203 patent is directed to methods of administering a pharmaceutical composition comprising a dose of desmopressin, sufficient to achieve *inter alia*, a maximum plasma/serum concentration no greater than 10 pg/mL. (*See, e.g.*, Exhibit C at 28:7-14.) The other independent claims of the '203 patent are similar but specify a particular route of delivery, namely transmucosal, transdermal, or intradermal.

66. The '321 patent issued from the'074 Application, which is a continuation of the '615 Application (filed on May 4, 2007), which is a division of the '100 Application, which is a continuation-in-part of PCT '463.

67. The '321 patent claims priority to PCT '463, which purports to claim priority to Ferring's GB '397.

68. The '321 patent lists Dr. Fein as the sole inventor.

69. The ’321 patent includes claims directed to, *inter alia*, methods for inducing voiding postponement in a patient comprising delivering to the bloodstream an amount of desmopressin no more than about 1 or 2 ng/kg by intranasal, transdermal, intradermal, transmucosal or conjunctival administration to produce an effect lasting for no more than about 4 and 6 hours. (*See, e.g.*, Exhibit D at 28:33-40, 59-63; 30:4-15.)

70. The ’761 patent issued from the ’100 Application, which is a continuation-in-part of PCT ’463.

71. The ’761 patent purports to claim priority to GB ’397.

72. The ’761 patent lists Dr. Fein as the sole inventor.

73. The claims of the ’761 patent recite compositions, comprising up to 1 µg desmopressin, including compositions dispensed by intranasal, transdermal, or intradermal administration. (*See, e.g.*, Exhibit E at 28:39-42.) The claims of the ’761 patent also recite compositions that, when administered to a patient, purportedly establish a steady plasma/serum desmopressin concentration in the range from about 0.1 picograms per mL plasma/serum to about a maximum of 10 picograms per mL plasma/serum. (*See, e.g.*, Exhibit E at 28:51-55, 56-60, 61-67; 29:7-15.)

FACTUAL BACKGROUND

Nocturia and Treatment with Desmopressin

74. Nocturia is generally defined as the need to wake more than once during the night to urinate (void), following an initial period of sleep. The prevalence of nocturia increases with age. Until recently, there were no products approved in the United States for the treatment of nocturia. Outside the United States, over 70 countries around the world have approved desmopressin for the treatment of adults with nocturia.

75. Desmopressin is a synthetic analog of the antidiuretic hormone vasopressin. Desmopressin results in concentrated urine and less water excretion. The FDA has already approved desmopressin in a number of dosage forms (*e.g.*, nasal solutions, tablets, and injectables) for the treatment of a variety of conditions such as central diabetes insipidus ("CDI"), a condition which causes excessive production of severely diluted urine, and primary nocturnal enuresis ("PNE"), more commonly known as bedwetting in children.

76. Desmopressin has been associated with the risk of hyponatremia or low sodium levels in blood. Symptoms associated with hyponatremia include nausea, headache and lethargy, but in severe cases it can result in seizures, coma, and death.

Serenity's NOCTIVA (desmopressin) Product

77. On February 4, 2016, Serenity submitted New Drug Application ("NDA") No. 201656 to the FDA under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act seeking approval for SER120, a desmopressin nasal spray to treat nocturia in adults (specifically, desmopressin nasal spray, 0.83 mcg/0.1 mL and 1.66 mcg/0.1 mL). A true and correct copy of a March 3, 2017, letter from Hylton V. Joffe to Serenity Pharmaceuticals, LLC, is attached as Exhibit F. The FDA's Division of Bone, Reproductive, and Urologic Products ("DBRUP") within the Center for Drug, Evaluation, and Research ("CDER") reviewed NDA 201656.

78. On March 3, 2017, the FDA granted final approval for Serenity's NDA for SER120, which Serenity intends to market and sell under the tradename NOCTIVA. (*Id.*)

79. The FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") lists, *inter alia*, the Patents in Suit as covering NOCTIVA.

Ferring's Long History with Desmopressin

80. Ferring is recognized as the innovator in the field of desmopressin. Ferring has developed and marketed several desmopressin products around the world, including products for nocturia. Ferring was the first company to develop desmopressin on an industrial scale and, in 1972, launched a nasal spray formulation of desmopressin it had developed for the treatment of CDI and, later, for PNE. Ferring continues to research and develop desmopressin dosage forms.

81. In the late 1980s, Ferring introduced a tablet dosage form of desmopressin, which is sold under the trade name MINIRIN, in countries outside the United States for the treatment of CDI and PNE. Ferring's MINIRIN tablet was the first oral dosage form of a peptide. Ferring was also able to introduce MINIRIN to the European market for the treatment of nocturia, first in Finland in 2001. MINIRIN tablets were available in 100 and 200 μg doses.

82. Ferring gained FDA approval of desmopressin tablets in the United States in 1995 (NDA 019955). In addition to NDA 019955, Ferring also has gained FDA approval of the following NDAs for desmopressin products for marketing in the United States under the tradename MINIRIN: 017922 (nasal solution); 018938 (injectable); 017922 (metered nasal spray); and 021333 (metered nasal spray).

83. As part of its position as the world leader in desmopressin research and development, Ferring continued its work to develop improved desmopressin products. As part of that work, Ferring began focusing its efforts on the development of a new orodispersible (orally disintegrating) tablet in the late 1990s to improve patient compliance, user convenience, bioavailability, and variability. Ferring secured its first marketing approval for this new orodispersible desmopressin tablet in Finland in August 2005, which Ferring named MINIRIN MELT and marketed in 60, 120, and 240 μg doses. Since then, Ferring has secured approval of

its MINIRIN MELT for PNE, CDI and nocturia. MINIRIN MELT is being sold in more than 70 countries, including dozens of countries in Europe.

84. Commensurate with Ferring's long history with desmopressin detailed in paragraphs 80-83, Ferring has expended substantial resources related to its development, regulatory approval, and ultimate commercialization of its desmopressin products.

Ferring's NOCDURNA

85. Ferring has been working over the last decades to develop a new desmopressin product for the treatment of nocturia. After developing first the MINIRIN tablet and later the orodispersible tablet MINIRIN MELT for nocturia, Ferring developed a gender specific low dose version of the melt formulation, which it named NOCDURNA. NOCDURNA is already on the market in Canada, Australia, and thirteen European countries.

86. On June 22, 2009, Ferring submitted NDA 022517 to the FDA seeking approval for NOCDURNA to treat nocturia in adults.

87. The NDA for NOCDURNA has an extensive review history. Unlike the Serenity NDA which was reviewed by DBRUP, the Ferring NDA was originally assigned to the Division of Metabolism and Endocrinology Products ("DMEP"), which had traditionally managed desmopressin products because of the drug's historical use in treating conditions related to diabetes. Over the course of three complete response letters, DMEP communicated to Ferring that the primary barrier to receiving final approval of the NDA for NOCDURNA was the need to establish the clinical significance of the drug effect shown in the clinical studies and to do so by incorporating a patient-reported outcome measure as a co-primary endpoint in a future clinical study.

88. On November 22, 2016, Ferring submitted a Citizen Petition to the FDA to express concern that, despite the two products' similar efficacy and safety profiles, the FDA "may be poised to apply its safety and efficacy standards" differently to SER120 than it had with NOCDURNA. A true and correct copy of Ferring's Citizen Petition is attached as Exhibit G. This was in part because the FDA reviews of the products were conducted by different divisions (DBRUP for SER120 and DMEP for NOCDURNA) and different advisory committees. The petition formally asked the FDA to establish a consistent standard for establishing the effectiveness of desmopressin products for the treatment of nocturia, "particularly for the purposes of determining whether the drug is clinically meaningful." (Exhibit G at 2.)

89. On Friday, March 3, 2017, the FDA approved Serenity's NDA 201656 and denied Ferring's Citizen Petition, but acknowledged and agreed with Ferring "that both applications raised questions as to whether the observed treatment effects are clinically meaningful." A true and correct copy of the March 3, 2017, letter from Janet Woodcock to Joan-Carles Arce is attached as Exhibit H; *see* Exhibit H at 8-9.

90. However, and quite remarkably, the FDA in the Citizen Petition response explained how it was able to reach a conclusion on the Serenity NDA that there is a clinically meaningful effect without the need to rely on a patient reported outcome measurement. That is, the FDA concluded a clinically meaningful benefit could be reached based solely on the data collected on the number of nocturnal voids per night, assessed over various periods of time and using various statistical measures, in the case of NDA 201656. (*Id.* at 9-10.)

91. The FDA then offered, for the first time, to allow Ferring to make a similar showing based on its existing data for NOCDURNA. (*Id.* at 10.) This is a significant departure for the FDA from all of the prior complete response letters from DMEP as now, for the first time,

the FDA indicated that Ferring could rely on its existing studies of NOCDURNA, and solely on its nocturnal void data, to establish a clinically meaningful benefit.

92. [redacted]

93. [redacted].

94. [redacted]

[redacted]

95. [redacted]

[redacted]

96. [redacted]

[redacted]

97. [redacted]

[redacted]

98. [redacted]

[redacted]

SUBJECT MATTER JURISDICTION

99. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338, based on an actual controversy between Ferring and Defendants for claims under the Patent Laws of the United States of America, 35 U.S.C. § 1 et seq. Ferring is seeking relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

The Extensive Litigation History between the Parties

100. Ferring and Defendants have an extensive and ongoing history of litigation in both the United States and Europe related to patents covering desmopressin, including related to patents claiming priority to Ferring's PCT '036, Fein's PCT '463, and/or Ferring's GB '397. For example, Ferring and Defendants have been litigating issues in (i) the U.S. District Court for the Southern District of New York (*Ferring B.V. et al. v. Allergan, Inc., et al.*, Case No. 12-cv-2650-RWS (S.D.N.Y., filed Apr. 5, 2012)), (ii) The Netherlands (Case No. 200.156.630-1, *Ferring B.V. v. Reprise Biopharmaceutics, LLC et al.* (Court of Appeal of The Hague); Case No. 200.156.625-1, *Ferring B.V. v. Allergan, Inc. and S.H. Fein* (Court of Appeal of The Hague); Case No. 200.113.960, *Allergan, Inc. et al. v. Ferring B.V.* (Court of Appeal of The Hague)), and (iii) the European Patent Office ("EPO") (Legal File No. R14-86/2011, *Reprise Biopharmaceutics LLC and Allergan Inc. v. Ferring B.V.* (involving Application Nos.: 03 781 836.6; 11 000 464.5; 11 000 465.2; 11 000 466.0; 11 000 467.8; 11 000 468.6) ("EPO Proceedings").

101. Defendants have engaged in a course of conduct that shows an immediate preparedness and willingness to enforce their patent rights against Ferring. Specifically, Defendants have made clear that they believe that NOCDURNA is covered by the claims of the Patents in Suit. For example, during prosecution of United States Patent Application No. 13/378,778 ("the '778 Application")—which the PTO issued as United States Patent No.

9,539,302 and which also lists Dr. Fein as the sole inventor—applicants referred to Ferring's development of NOCDURNA as being "in open defiance of Dr. Fein's patents" in reference to patents that include the Patents in Suit. (A true and correct copy of the July 5, 2016, Response to Office Action from the prosecution of the '778 Application is attached as Exhibit J; *see* Exhibit J at 12.) Dr. Fein himself submitted a declaration in the same proceeding accusing Ferring's NOCDURNA of infringing activity: "in naked defiance of my patent rights [including in the Patents in Suit], Ferring designed a desmopressin low dose drug product [*i.e.*, NOCDURNA] in direct competition with Serenity/Allergan." (*Id.* at 19, ¶ 11.)

102. In letters submitted during the EPO Proceedings between Ferring and Defendants (and others), Allergan, Inc., and Reprise referred to Ferring's NOCDURNA and MINIRIN MELT as follows:

- "By way of example of the detrimental consequences of the stay of proceedings (and the comfortable position the Third Party [Ferring] has), we submit a press release relating to the Nocdurna product from Ferring. In the press release, Ferring states that:

  'NOCDURNA once-daily lyophilisate tablets are administered sublingually (without the need for water) in gender specific **low doses**, tailored specifically for men (50 mcg) and women (25 mcg).' (p. 1, 3rd par., emphasis added).

  Thus, in the time period that the patent applications in suit were stayed by the EPO (now more than 5 years, see below), Ferring has been developing a product which according to Ferring itself contains 'low doses' of desmopressin for the treatment of nocturia, which is the subject matter of the stayed [patent] applications. Ferring has been able to do this in the undeservedly comfortable position of not having to fear a law suit being brought for patent infringement by Reprise and/or Allergan because there is no granted patent [in

Europe].” (A true and correct copy of a letter dated October 7, 2016, from Allergan and Reprise to the EPO is attached as Exhibit K; *see* Exhibit K at 3-4.)

- Ferring “does not inform the EPO that its Minrin (or Minirin) Melt products sold in Europe infringe the claims of the [patent] application. Ferring markets a low dose desmopressin formulation for use in adult nocturia which fulfills all the elements of the claim. Hence, Ferring is infringing. . . . What Ferring fails to bring forward is that their Minrin (or Minirin) product infringes the current claims of the application in suit. Any delay in the proceedings to grant of the current [patent] application serves merely to protect the interest of escaping an infringement claim by Allergan. . . . [I]t is a fundamental right to be able to exploit ones property and to prosecute infringers thereon. By staying the application, this right is denied to the Applicant.” (A true and correct copy of a letter dated September 12, 2011, from Allergan to the EPO is attached as Exhibit L; *see* Exhibit L at 3-4.)
- “The fact that the Third Party [Ferring] is infringing . . .. The Third Party [Ferring] offers for sale in the EPC contracting states a desmopressin product that falls under the claims of the now suspended application (Minirin Melt). By preventing the application to proceed to grant, the Third Party [Ferring] is avoiding infringement proceedings being initiated against it and/or is avoiding the obligation to pay royalties.” A true and correct copy of a letter dated December 20, 2011, from Allergan and Reprise to the EPO is attached as Exhibit M; *see* Exhibit M at 7.

NOCDURNA and FDA Approval

103. Ferring continues to expend substantial resources in securing FDA approval of NOCDURNA. Ferring will continue expending substantial resources throughout the approval process, as well as through launch and marketing of NOCDURNA.

104. Given the FDA's suggestion to Ferring that it is willing to work with Ferring to reassess the clinical benefit data applying consistent standards for efficacy and safety—as Ferring requested in its Citizen Petition—and acknowledged similar efficacy and safety profiles of NOCTIVA and NOCDURNA, there is a very high expectation of success in obtaining regulatory approval for NOCDURNA in the near future.

105. [redacted]

106. In view of the pending status of NDA 022517 and FDA's review of clinical data already available from clinical trials conducted by Ferring, the attributes of NOCDURNA relevant to the limitations of the claims in the Patents in Suit will not change prior to FDA approval, or any offer for sale or sale of NOCDURNA.

The Adverse Legal Interests Between the Parties

107. As set forth above, Defendants have explicitly and directly expressed the intent to enforce the Patents in Suit against Ferring.

108. Ferring and Defendants have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity, unenforceability, and non-infringement of the Patents in Suit.

109. There is a substantial controversy between Ferring and Defendants that is sufficiently definite and concrete to require conclusive judicial resolution regarding the invalidity, unenforceability, and non-infringement of the Patents in Suit.

COUNT I

(Declaratory Judgment of Invalidity of the Patents in Suit Under 35 U.S.C. § 102)

110. Paragraphs 1 to 109 are incorporated herein as set forth above.

111. An actual and justiciable case or controversy exists between Ferring and Defendants regarding the invalidity of the Patents in Suit.

112. Ferring's decades-long research and development of desmopressin work is extensively documented and shows that (i) PCT '036 does not cover any purported inventions by Dr. Fein, (ii) relative to the Patents in Suit, PCT '036 is the work of another, and (iii) Dr. Fein did not make any inventive contribution to the Patents in Suit.

113. The Patents in Suit may claim priority no earlier than May 6, 2003.

114. Under 35 U.S.C. § 102(e), WO '885 is prior art as of its filing date, September 20, 2002. Therefore, WO '885 is prior art to PCT '463 under 35 U.S.C. § 102(e).

115. The claims of each of the Patents in Suit are anticipated by and/or rendered obviousness over WO '885 in combination with the common knowledge in the art.

116. Dr. Fein did not himself invent the subject matter claimed in the Patents in Suit.

117. The claims of the Patents in Suit are invalid for failure to comply with the conditions for patentability set forth in 35 U.S.C. § 102(f).

COUNT II
(Declaratory Judgment of Invalidity of the Patents in Suit for Lack of Enablement Under 35 U.S.C. § 112, ¶ 1)

118. Paragraphs 1 to 109 are incorporated herein as set forth above.

119. The specifications of the Patents in Suit fail to enable a person of ordinary skill in the art to make and use the inventions defined by the claims of the Patents in Suit as exemplified in paragraphs 120-125.

120. The specifications of the Patents in Suit fail to enable one of ordinary skill in the art absent undue experimentation to make and administer dosage forms to use in the claimed methods to (i) achieve the claimed plasma/serum concentrations; (ii) deliver claimed amounts of desmopressin to the bloodstream; (iii) treat nocturia, primary nocturnal enuresis, or incontinence; and (iv) achieve the claimed duration of action. (*See, e.g.,* Exhibit C, claims 1 (28:7-14), 10 (28:32-37), 13 (28:45-51).)

121. Further, the specifications of the Patents in Suit also fail to enable one of ordinary skill in the art, absent undue experimentation, to select, make, and/or administer, dosage forms that can achieve a maximum desmopressin plasma/serum concentration no greater than 10 pg/mL by the claimed routes of administration (*i.e.,* transmucosal, transdermal, or intradermal delivery). (*See, e.g.,* Exhibit C, claims 2, 6-8, 10, 13.)

122. The specifications of the Patents in Suit also fail to enable one of ordinary skill in the art to make and administer dosage forms to use in the claimed methods, absent undue experimentation, to achieve the claimed "steady" plasma/serum desmopressin concentration

range through intranasal, transdermal, or intradermal administration. (*See, e.g.*, Exhibit E, claims 1-4, 7, 9, 11-17.)

123. The specifications of the Patents in Suit also fail to enable one of ordinary skill in the art to induce voiding postponement in a patient while reducing the risk that the patient develops hyponatremia. (*See, e.g.*, Exhibit D, claims 1-7 and 19-21.)

124. On information and belief, Dr. Fein has admitted that the Patents in Suit are not enabled. For example, on January 22, 2016, Dr. Fein argued that the Patents in Suit failed to address a problem purportedly solved by the subject matter claimed in the '778 Application. (A true and correct copy of the January 22, 2016, Request for Continued Examination from the prosecution of the '778 Application is attached as Exhibit N.) Specifically, Dr. Fein argued that the Patents in Suit failed to enable delivery of a low dose of desmopressin to patients to achieve a desmopressin blood concentration sufficient to treat nocturia effectively and safely. (*Id.* at 6.)

125. Dr. Fein submitted a declaration dated June 30, 2016, during prosecution of the '778 Application, in which he stated that (i) the purported inventions claimed in the Patents in Suit demonstrated a need for a low dose desmopressin product for the treatment of nocturia (ii) but that Ferring had not secured FDA approval for a similar invention (*i.e.*, NOCDURNA) and (iii) thus, according to Dr. Fein, there was a long-felt need for a low dose desmopressin product for the treatment of nocturia until the filing of the '778 Application. (*See* Exhibit J at, *e.g.*, 17-20, ¶¶ 7-13.) Moreover, Applicant(s), in response to the Office Action, adopted the arguments in Dr. Fein's declaration. (*Id.* at, *e.g.*, 12.) As the PTO acknowledged, Dr. Fein himself argued that the inventions claimed in the Patents in Suit were not enabled until 2010. (A true and correct copy of the July 20, 2016, Office Action from the prosecution of the '778

Application is attached as Exhibit O; *see, e.g.,* Exhibit O at 9, citing Dr. Fein's June 30, 2016, declaration at ¶¶ 7, 13.)

126. The claims of the Patents in Suit are invalid under 35 U.S.C. § 112, ¶ 1 for a lack of enablement.

COUNT III
(Declaratory Judgment of Invalidity of the Patents in Suit for Inadequate Written Description Under 35 U.S.C. § 112, ¶ 1)

127. Paragraphs 1 to 109 are incorporated herein as set forth above.

128. The specifications of the Patents in Suit fail to provide an adequate written description of the full scope of the claimed inventions as exemplified in paragraph 129 below.

129. The specifications of the Patents in Suit fail to provide an adequate written description to support (i) achieving the claimed plasma/serum concentrations by all claimed routes of administration (*e.g.,* transmucosal, transdermal, intradermal, intravenous, subcutaneous, intranasal) (*see, e.g.,* Exhibit C, claims 1-15; Exhibit D, claims 15-16) or (ii) all indications purportedly treated by the claimed methods (*see, e.g.,* Exhibit C, claims 1-9, 11; Exhibit D, claims 5 and 18).

130. Further, the specifications of the Patents in Suit fail to provide an adequate written description for the same reasons provided in paragraphs 120-125, incorporated fully herein, which shows that Applicants were not in possession of the claimed inventions.

131. The claims of the Patents in Suit are invalid under 35 U.S.C. § 112, ¶ 1 for failing to provide an adequate written description.

COUNT IV
(Declaratory Judgment of Invalidity of the Patents in Suit Under 35 U.S.C. § 112, ¶ 2)

132. Paragraphs 1 to 109 are incorporated herein as set forth above.

133. The claims of the Patents in Suit are indefinite as exemplified in paragraphs 134-136 below.

134. Claims in the Patents in Suit require transmucosal, transdermal, or intradermal delivery of desmopressin (*see, e.g.*, Exhibit C, claims 2, 6-8, 10, 13) but these claims fail to particularly point out and distinctly claim the invention. The specification provides no context for "delivery." The limitations claiming transmucosal, transdermal, or intradermal delivery are indefinite.

135. Claims of the Patents in Suit recite a method for inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia (*see, e.g.*, Exhibit D, *e.g.*, claim 1-7 and 19-21) but these claims fail to particularly point out and distinctly claim the invention. The specification provides no information on how to measure such risk and how to ascertain if it has been reduced. The limitations claiming a reduction of risk are indefinite.

136. Claims of the Patents in Suit claim a pharmaceutical composition sufficient to establish a steady plasma/serum desmopressin concentration in certain ranges (*see, e.g.*, Exhibit E, claim 5-17) but these claims fail to particularly point out and distinctly claim the invention. The specification provides no context or basis to determine what "steady" means. The limitations claiming a steady plasma/serum desmopressin concentration are indefinite.

137. The claims of the Patents in Suit are invalid under 35 U.S.C. § 112, ¶ 2 for indefiniteness.

COUNT V
(Declaratory Judgment of Unenforceability of the Patents in Suit)

138. Paragraphs 1 to 109 are incorporated herein as set forth above.

139. An actual and justiciable case or controversy exists between Ferring and Defendants regarding the enforceability of the Patents in Suit.

140. Dr. Fein made intentional misrepresentations and omissions during the prosecution of the Patents in Suit by, *inter alia*, (i) repeatedly falsely stating under oath that he was the sole inventor of the subject matter claimed in the Patents in Suit, (ii) submitting a false claim of priority for the subject matter claimed in the Patents in Suit, and (iii) failing to disclose the existence of an inventorship dispute with Ferring over the subject matter claimed in the Patents in Suit. On information and belief, these misrepresentations and omissions were made with the intent to deceive the PTO.

141. Dr. Fein signed a Combined Declaration and Power of Attorney for Sole Inventor ("Combined Declaration") in which he claimed to be the sole inventor of the inventions claimed in the '100 Application. (A true and correct copy of the Combined Declaration downloaded from the PTO's Public Pair site (http://portal.uspto.gov/pair/PublicPair) for the '761 patent is attached as Exhibit P.) Dr. Fein signed his Combined Declaration on March 19, 2004, acknowledging "the duty to disclose information which is material to patentability in 37 C.F.R. 1.56," and recognizing that any willful false statements "may jeopardize the validity of the application and any patent issuing thereon." (*Id.*)

142. Dr. Fein first submitted his declaration—again, which he signed on March19, 2004—on March 29, 2004, during prosecution of the application that ultimately issued as the '761 patent (*see* Exhibit P). He submitted it again on July 26, 2007, during prosecution of the application that ultimately issued as the '203 patent (a true and correct copy of the Combined Declaration downloaded from the PTO's Public Pair site for the '203 patent is attached as Exhibit Q), and submitted it again on July 15, 2008, during prosecution of the application that ultimately issued as the '321 patent (a true and correct copy of the Combined Declaration downloaded from the PTO's Public Pair site for the '321 patent is attached as Exhibit R).

143. At the times Dr. Fein signed and submitted his Combined Declaration, he knew that (i) he was not the sole inventor of the subject matter claimed in the Patents in Suit, (ii) his claim of priority for the subject matter claimed in the Patents in Suit was false, and (iii) his claim to sole inventorship of the subject matter claimed in the Patents in Suit was disputed by Ferring.

144. A central example in the Patents in Suit is Example 8, which describes a clinical study designed to evaluate the "antidiuretic effect of three low doses of desmopressin administered via intravenous infusion for 2 hours in over-hydrated, healthy, non-smoking male and female volunteers." (Exhibit C at col. 20:39-42.) Dr. Fein did not conceive of Example 8; Example 8 is essentially a copy of a Ferring clinical study protocol for a Ferring clinical study called CS009. A simple comparison of the Ferring CS009 clinical study protocol to Example 8 demonstrates that (i) both have the same primary objective, (ii) the methodologies used are essentially the same, including relatively small number of subjects healthy, overhydrated, non-smoking male and female volunteers with ascending similar low doses, (iii) both use the same route of administration, i.v., (iv) both have the same duration of treatment, and (v) both evaluate the same endpoints. Therefore, Dr. Fein knew that Example 8 was conceived of and reduced to practice by Ferring. The inventions claimed in the Patents in Suit rely on Example 8 for patentability. For example, the specification itself relies on Example 8 as justification for the claimed doses and concentrations for various routes of administration. (*See* Exhibit C at col. 25:63-65, 26:63-27:3; *see also id.* at 27:48-51 (stating that Example 8 "demonstrates that desmopressin can produce this essential antidiuretic effect at much lower doses and lower blood concentrations than previously thought")) *see also, e.g.*, Exhibit S (a true a correct copy of the April 8, 2008, Amendment and Response to Office Action in the file history for the '761 patent), at 16 of 22 (referring the Examiner to Example 8 for disclosure of "administration to achieve a

desmopressin blood concentration within the range claimed and show[ing] specifically the antidiuretic effect"); Exhibit T (a true a correct copy of the July 15, 2008, Preliminary Amendment in the file history for the '321 patent) at 6 of 7 (stating that support of the claimed subject matter can be found, *inter alia*, in Example 8 "for subject matter of *antidiuretic effect*"); Exhibit U (a true a correct copy of the Response to Office Action in the reexamination of the '302 patent) at 3 (stating that "[f]rom these studies [Example 8], it was established that the threshold desmopressin blood concentration sufficient to produce an anti-diuresis effect was much lower than the concentrations typically achieved in prior art practice").

145. Example 8 was not included in the priority application, GB '397, or even PCT '463. In fact, Example 8 was not added to the specification of any document in the chain of priority for the patents in suit until November 12, 2003, when Dr. Fein filed the '100 Application. Dr. Fein was aware that Example 8 was crucial for patentability of the patents in suit and that it was not included until November 2003. Dr. Fein deliberately provided the PTO with an improper priority claim during prosecution of the Patents in Suit. For example, in Dr. Fein's sworn Combined Declaration, Dr. Fein claimed foreign priority benefits under 35 U.S.C. § 119 to GB '397. Dr. Fein knew the priority claim was false. On information and belief, Dr. Fein claimed priority to GB '397 with an intent to deceive the PTO.

146. Dr. Fein knew that there was an inventorship dispute with Ferring, at least over Example 8, which was conceived by others but crucial to the patentability of the patents in suit, and made a deliberate decision to withhold the dispute from the PTO. The single most reasonable inference is that Dr. Fein had the specific intent to deceive the PTO.

147. During prosecution, examiners are required to consider the requirements of all sections of 35 U.S.C., including § 102(f). Dr. Fein had a duty to disclose material information

related to patentability, which includes information related to inventorship conflicts. *See, e.g.*, *Manual Patent Examining Procedure*, § 2001.04. The duty of disclosure under 37 C.F.R. § 1.56 applies to all dealings with the PTO, including prosecution of the applications that ultimately issued as the Patents in Suit, which includes prosecution through issuance and the reexamination of the '203 patent.

148. Dr. Fein breached or otherwise failed to satisfy his duty to disclose material information and breached or otherwise failed to satisfy his duty of candor before the PTO during prosecution of the Patents in Suit by, *inter alia*, submitting misleading, improper, and/or false claims of inventorship and/or priority, and/or failing to disclose material information. On information and belief, Dr. Fein acted with an intent to deceive the PTO during prosecution of the Patents in Suit.

COUNT VI
(Declaratory Judgment of Noninfringement of the Patents in Suit)

149. Paragraphs 1 to 109 are incorporated herein as set forth above.

150. An actual and justiciable case or controversy exists between Ferring and Defendants regarding whether Ferring's NOCDURNA infringes the claims of the Patents in Suit.

151. Ferring's NOCDURNA and the use of Ferring's NOCDURNA do not and will not infringe any valid claim of the Patents in Suit as properly construed.

152. Ferring does not and will not directly or indirectly (*e.g.*, by inducement) infringe any valid claim of the Patents in Suit as properly construed.

PRAYER FOR RELIEF

WHEREFORE, Ferring respectfully requests the following judgment and relief:

a. A declaration be issued under 28 U.S.C. § 2201 that the claims of the '203 patent are invalid for failure to comply with one or more of the conditions for patentability set forth

in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102(e), 102(f), 112, ¶ 1, and 112, ¶ 2;

b. A declaration be issued under 28 U.S.C. § 2201 that the ’203 patent is unenforceable due to inequitable conduct during prosecution of the application that issued as the ’203 patent and/or during reexamination of the ’203 patent;

c. A declaration be issued that Ferring’s NOCDURNA does not infringe any claim of the ’203 patent;

d. That an injunction be issued enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Ferring or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Ferring, or charging them either orally or in writing with infringement of the ’203 patent;

e. A declaration be issued under 28 U.S.C. § 2201 that the claims of the ’321 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102(e), 102(f), 112, ¶ 1, and 112, ¶ 2;

f. A declaration be issued under 28 U.S.C. § 2201 that the ’321 patent is unenforceable due to inequitable conduct during prosecution of the application that issued as the ’321 patent;

g. A declaration be issued that Ferring’s NOCDURNA does not infringe any claim of the ’321 patent;

h. That an injunction be issued enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Ferring or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Ferring, or charging them either orally or in writing with infringement of the ’321 patent;

i. A declaration be issued under 28 U.S.C. § 2201 that the claims of the ’761 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102(e), 102(f), 112, ¶ 1, and 112, ¶ 2;

j. A declaration be issued under 28 U.S.C. § 2201 that the ’761 patent is unenforceable due to inequitable conduct during prosecution of the application that issued as the ’761 patent;

k. A declaration be issued that Ferring’s NOCDURNA does not infringe any claim of the ’761 patent;

l. That an injunction be issued enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Ferring or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Ferring, or charging them either orally or in writing with infringement of the ’761 patent;

m. A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding Ferring its reasonable attorneys’ fees, costs, and expenses; and

n. Any and all other and further relief as this Court deems just and proper.

Redacted Version Filed: July 7, 2017

Dated: June 30, 2017

/s/ Mary W. Bourke

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CERTIFICATE OF SERVICE

I hereby certify that on the 30th day of June, 2017, I electronically filed a true and correct copy of the foregoing **AMENDED COMPLAINT FOR DECLARATORY JUDGMENT** via CM/ECF and electronically mailed a copy to the below individuals:

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